REMARKS

This amendment is submitted in response to the Office Action mailed May 14, 2008, in connection with the above-identified application (hereinafter, the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on August 14, 2008. Accordingly, this amendment is timely submitted.

Product claims 1-4, 7-11, 13-14, 16-17, 23-28, of which claims 1-3, 17, 23-25, and 28 are independent, remain pending and appear in this application for the Examiner's review and consideration. Claims 5, 15, and 29 have been cancelled. Claims 1-3, 14, 16-17, 23-26 and 28 have been amended to provide clarity and to recite additional embodiments of the presently-claimed invention.

Product claims 6 and 12 and process claims 18-22 remain withdrawn. With respect to process claims 18-22, Applicant, however, understands that these claims will be rejoined and allowed when product claim 3, from which they depend, is allowed. To place the claims in condition for allowance after rejoinder, process claims 18-22 have been amended to depend on product claim 3.

Applicant does not acquiesce in the correctness of the rejections or objections, and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

Support for the amendments is found throughout the entire specification, for example, at page 1, [0013], lines 1-6 and [0016] to page 2, lines 1-5; page 2, [0019], lines 1-7; page 3, [0032], lines 1-4; page 4, [0056], line 3 and 18; and page 6, [0077] lines 7-9 and [0085], lines 10-11 of the published patent application, US 2004/0087490A1.

Applicant respectfully submits that the rejections based on lack of written description, indefiniteness, lack of novelty and obviousness are overcome in view of the amendments and arguments presented in the response. Applicant, therefore, respectfully requests that all amendments be entered at this time and reconsideration of this application in view of the above amendments and the following remarks presented hereinbelow.

Rejections Based on 35 U.S.C. §112, First and Second paragraphs

Claims 17 and 28 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the "generic statement anti-cancer drug does not provide ample written description for the compounds since the claims do not describe a single structural feature." To address the Examiner's concerns, Applicant has cancelled claim 29 and incorporated the recited features of the cancelled claim into claims 17 and 28. In view of the amendments, the rejection is rendered moot. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the rejection based on 35 U.S.C. §112, first paragraph.

Claims 3 and 25 are rejected under 35 U.S.C. §112, second paragraph, for being allegedly indefinite with respect to the recitation of the phrase "the ratio of the intact protein to leucine in free form and/or salt forms." In response, these claims have been amended by adding the phrase "leucine and" after the preamble and before the phrase "at least one essential amino acid...." Similar amendments are applied to kit claims 17 and 28. Accordingly, the withdrawal of the indefiniteness rejection is earnestly requested.

Rejections Based on Anticipation

Claim 23-24 are rejected under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 4,498,879 to Madsen et al. (referred hereinafter as "Madsen"). Applicant respectfully disagrees with the rejection.

Madsen generally describes and suggests a nutritional composition that "comprises about 19.4 to 19.8% of leucine and about 1.1 to 1.2% methionine" and "that essential amino acids should comprise about from 60-75% by weight of the total amino acids." Contrary to Madsen, claims 23 and 24, as amended, are drawn to compositions that consist essentially of leucine and at least one essential amino acid in free and/or salt form, wherein leucine in free and/or salt form and total leucine, respectively, are both present in an amount of at least about 25% by weight based on the weight of the total amino acids. Accordingly, Madsen's leucine level is lower than that of the claimed compositions.

"To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently." *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

In view of the claim amendments and remarks presented hereinabove, Applicant respectfully submits that Madsen fails to anticipate claims 23 and 24. Accordingly, withdrawal of the rejection of these claims is respectfully requested.

The Office Action has rejected claims 3-5, 7, 25 and 27 under 35 U.S.C. §102(e) and §102(a), as being anticipated by U.S. Patent No. 6,420,342 to Hageman et al. (referred hereinafter as "Hageman"). Applicant respectfully disagrees with the rejection.

Hageman generally describes and suggests a nutritional, pharmaceutical or dietetic preparation that includes effective amounts of ribose and folic acid, optionally combined with other components, such as niacin, histidine, glutamine, orotate, vitamin B6 and other components. See Hageman Abstract. Hageman also discloses and suggests products for sportsmen having the following mixture of amino acids that appeared to be especially beneficial for muscle growth when consumed in an amount of more than 2 and preferably more than 4 g per daily dose: 3-10 wt % histidine, 5-15 wt % isoleucine, 10-23 wt % leucine, 10-23 wt % lysine, 5-15 wt % methionine, 5-15 wt % phenylalanine, 5-15 wt % threonine. See Hageman, at column 6, line 62-column 7, line 1. In contrast, the presently-claimed invention, as set forth in amended independent claims 3 and 25, as well as dependent claims 4, 7 and 27, are drawn to compositions that provide (1) leucine, either in free and/or salt form, at a concentration of at least about 25%, and (2) a ratio of total essential amino acids and, optionally, conditionally essential amino acids to total amino acids that ranges from about 0.60 to about 0.90. The level of leucine in Hageman's composition is 23%, the amount of which is lower than that of the claimed compositions, as encompassed in amended claims 3 and 25, as well as dependent claims 4, 7 and 27. Hagemen also fails to disclose and suggest a composition that provides a ratio of total essential amino acids and, optionally, conditionally essential amino acids to total amino acids that ranges from about 0.60 to about 0.90.

In view of the claim amendments and remarks presented hereinabove, Applicant respectfully submits that Hageman fails to describe and suggest each and every element of the presently-claimed compositions. Accordingly, Applicant respectfully requests that the Examiner

reconsider and withdraw the rejection of claims 3, 4, 7, 25 and 27 in view of Hageman. The cancellation of claim 5 renders the rejection of this claim moot.

Claims 3-4, 7-11, 15 and 26 are rejected under 35 U.S.C. §102(e) and §102(a), as being anticipated by U.S. Patent No. 6,387,883 to Abbruzzese et al. (referred hereinafter as "Abbruzzese"). Applicant respectfully disagrees with the rejection for the following reasons provided hereinbelow.

Abbruzzese generally describes and suggests methods and nutritional compositions for preventing and treating cachexia and anorexia. Abbruzzese's composition includes effective amounts of (1) ω-3 fatty acids, such as α-linolenic acid, stearidonic acid, eicosapentaenoic acid, docosapentaenoic acid, docosahexaenoic acid or mixtures thereof; (2) branched-chain amino acids, such as valine, leucine, isoleucine or mixtures thereof; with or without reduced levels of tryptophan and 5-hydroxytryptophan; and (3) an anti-oxidant system selected from the group consisting of beta-carotene, vitamin C, vitamin E, selenium, or mixtures thereof. See Abbruzzese's Abstract.

In an amino acid profile for an Abbruzzese's nutritional composition, the amount of leucine is 9.08 g/100 g protein (i.e. percent). See Abbruzzese at column 9, line 17. In contrast, the amount of leucine in free and/or salt form, provided by the presently-claimed composition and as set forth in amended claim 3, as well as the claims that depend therefrom, is at least about 25%. This amount is obviously higher than that of Abbruzzese. Furthermore, the presently-claimed composition requires a ratio of total essential amino acids and, optionally, conditionally essential amino acids to total amino acids that ranges from about 0.60 to about 0.90. In Abbruzzese's composition, the ratio of total essential amino acids and conditionally essential amino acids to total amino acids is 0.51. This ratio is much lower than that of the present invention, as claimed.

In view of the remarks provided and claim amendments, Applicant respectfully submits that Abbruzzese, similar to Hageman, fails to describe and teach each and every element of present invention. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of rejection of claims 3-4, 7-11 and 26. The rejection of claims 15 is moot in view of the cancellation of the claim.

Rejections Based on Obviousness

The Office Action rejected claims 13-14 and 16 under 35 U.S.C §103(a) as being unpatentable over Abbruzzese. Applicant respectfully disagrees with this rejection.

The various deficiencies of Abbruzzese as a reference have been enumerated above. The above arguments applied to rebut the Examiner's anticipation rejection based on Abbruzzese are incorporated herein to demonstrate further deficiencies of Abbruzzese as a cited reference.

Applicant respectfully submits that Abbruzzese fails to describe or suggest the claimed compositions that comprise (a) leucine, either in free and/or salt form, in the amount of at least about 25%; and (b) a ratio of total essential amino acids and, optionally, conditionally essential amino acids to total amino acids ranging from about 0.60 to about 0.90. "Where the prior art gives no indication which parameters are critical and no direction as to which many possible choices is likely to be successful, the fact that the claimed combination falls within the scope of possible combinations taught therein does not render it unpatentably obvious." *In re O'Farrell*, 7 U.S.P.Q. 2d 1673 (CAFC 1988). Applicant respectfully submits that one of ordinary skill in the art, upon reading the Abbruzzese reference, would not have the knowledge nor motivation to arrive at the presently-claimed composition. Nor would there be any expectation of success to practice or use the claimed compositions. The total lack of direction toward the subject matter of the present invention, as currently claimed, renders Abbruzzese inapplicable to an obviousness rejection.

In view of the foregoing remarks and claim amendments, Applicant respectfully submits that Abbruzzese, like the Madsen and Hageman references, also fails to describe or suggest the subject matter of claims 13-14 and 16. *See* MPEP 2143.03. ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art").

Claims 1-2 are rejected as being unpatentable for obviousness over Madsen. Applicant respectfully disagrees with the rejection. The many deficiencies of Madsen as a reference have been enumerated above. The above-mentioned arguments applied to rebut the anticipation rejection based on Madsen are incorporated hereinbelow.

As in claims 23 and 24, claims 1 and 2, as amended, are directed to compositions that

include leucine and at least one essential amino acid in free and/or salt form, wherein leucine, either in free and/or salt form, and total leucine, respectively, are both present in an amount of at least about 25% by weight based on the weight of the total amino acids. The level of leucine in Madsen's composition is lower than that of the claimed compositions. As required, the ratio of total essential amino acids to total amino acids, according to the presently-claimed composition, ranges from about 0.60 to about 0.90. In contrast, Madsen's composition has a ratio of 0.51, the value of which is lower than that of the presently-claimed compositions.

In view of the above and claim amendments, one of ordinary skill in the art, following Madsen's teachings, would not be motivated and reasonably expect any success to arrive at the claimed invention. Thus, Madsen fails to render obvious the present invention, as currently claimed. Applicant respectfully requests the withdrawal of the obviousness rejection of claims 1 and 2.

The Office Action have rejected kit claims 17, 28 and 29 as being unpatentable for obviousness over Hageman, in view of U.S. Patent No. 6,953,679 to Salvati et al. (referred hereinafter as "Salvati"). Applicant respectfully disagrees with the rejection.

The deficiencies of Hageman as a prior art are provided hereinabove. The above-mentioned arguments applied to overcome the anticipation rejection based on Hageman are incorporated hereinbelow.

The presently-claimed invention, as set forth in amended kit claims 17 and 28, requires that (1) the amount of leucine, either in free and/or salt form, is at least about 25%, and (2) a ratio of total essential amino acids and, optionally, conditionally essential amino acids to total amino acids that ranges from about 0.60 to about 0.90. As pointed out above, the level of leucine in Hageman's composition is lower (23%) than that of the claimed compositions (about 25%). Hagemen also fails to disclose and suggest a composition that provides a ratio of total essential amino acids and, optionally, conditionally essential amino acids to total amino acids that ranges from about 0.60 to about 0.90. In addition to these deficiencies, Hageman fails to disclose and suggest the kits, as encompassed by claims 17 and 28, that include an anti-cancer drug. To cure these deficiencies, the Office Action cited Salvati as a secondary reference.

Salvati generally describes fused cyclic compounds and methods of using such compounds in the treatment of nuclear hormone receptor-associated diseases such as cancer and

immune disorders and pharmaceutical compositions containing such compounds. See Salvati's Abstract. Like Hageman, Salvati also fails to disclose and suggest the claimed kits wherein the level of leucine is at least about 25% and the ratio of total essential amino acids and, optionally, conditionally essential amino acids, to total amino acids that ranges from about 0.60 to about 0.90. Accordingly, Salvati fails to remedy the above-mentioned deficiencies of Hageman. One of ordinary skill in the art would not be motivated to combine the teachings of Hageman with that of Salvati, to arrive at the presently-claimed kit, as set forth in amended claims 17 and 28. In view of the above remarks and claim amendments, claims 17 and 28 are not rendered obvious by the combination of both references.

Claim 29 has been cancelled. The rejection of this claim is now moot.

Applicant respectfully submits that the present invention, as claimed herein, is neither anticipated by nor rendered obvious in view of the Madsen, Hageman, Abbruzzese, and Salvati references. Reconsideration and withdrawal of the §112, first and second paragraphs, §102 and 103 rejections are earnestly requested.

CONCLUSION

For at least the reasons set forth above, Applicant respectfully submits that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicant's representative designated below.

The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.17 which may be required, or credit any overpayment, to deposit account no. 50-4498 in the name of Nestle Nutrition.

Respectfully submitted,

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